

AUG 9 2000

K001492 p.1/2



### 510(k) Summary

1. Name: Quinton Instrument Company
2. Address: 3303 Monte Villa Parkway  
Bothell, WA 98021-8906
3. Phone number: (425) 402-2484
4. Fax number: (425) 402-2017
5. Contact person: David Himes
6. Summary prepared: 5/11/00
7. Proprietary name: Q-Stress
8. Common name: Stress system
9. Classification name:
  - § 870.1425 Programmable diagnostic computer
  - § 870.2050 Biopotential amplifier and signal conditioner
  - § 870.2300 Cardiac monitor
  - § 870.2340 Electrocardiograph
  - § 870.2350 Electrocardiograph lead switching adapter
  - § 870.2600 Signal isolation system
  - § 870.2810 Paper chart recorder
  - § 870.2900 Patient transducer and electrode cable
10. The Q-Stress is substantially equivalent to the Q-4500 Stress Test Monitor (K910017).
11. Description: Q-Stress is a diagnostic device capable of ECG monitoring; ST analysis and ventricular ectopic beat detection; generation, review, and storage of stress reports; and treadmill or ergometer control. The device consists of a patient cable, preamplifier, CPU, display, modem, mouse, printer, keyboard, isolation power supply, and data collector. Approved serial devices such as non-invasive blood pressure measurement may be supported by the device. Electrocardiographic data is obtained by the preamplifier and sent to the CPU for processing. The user may generate reports for display or may opt to print results via a printer.
12. Intended use:
  - The device is intended to acquire, process, record, archive, analyze, and output electrocardiographic data during physiologic stress testing.



- The device may interface with external devices, including a treadmill or ergometer for dynamic exercise evaluation, non-invasive blood pressure equipment, and computer communications equipment.
- The device is intended for use in a clinical setting by trained personnel who are acting on the orders of a licensed physician.
- The device is to be used on adult populations, typically symptomatic.
- The device is not intended to be used as a vital signs physiological monitor.

13. Technological characteristic comparison: The Q-4500 Stress Test Monitor (K910017) and the proposed device have identical indications for use. Both devices are to be used on adult populations, typically symptomatic. Both devices utilize preamplifiers to collect electrocardiographic transducer information from the patient. The preamplifiers provide electrical isolation of the patient and the device. The Q-4500 utilizes a series of microprocessors to convert and process data for presentation to the operator. The proposed device utilizes a single microprocessor (Pentium) to achieve the same function. Most of the processes and algorithms of the Q-4500 have been preserved in the proposed device. However, beat classification and QRS detection algorithms have been changed for improved performance. The new algorithms were acquired from Zymed Incorporated from the Telemetry System: Model EasiView (K980186). The use of these algorithms represents an already proven performance enhancement. Both devices utilize biocompatible materials that come into contact with the patient (patient leads). The Q-4500 uses PVC while the proposed device utilizes Santoprene, a proven medical grade polymer. Stability testing of both devices shall be performed in accordance with IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety. Both devices are used in identical anatomical sites. Human factors for both devices are similar. Generated data is identical. However, the proposed device allows the user to configure data to a desired format. This enhancement has no affect on safety or efficacy. Both devices utilize medical grade power supplies to isolate the patient. The devices are for monitoring only. No energy is delivered to the patient. Electromagnetic compatibility conformance is ensured in accordance with IEC 60601-1-2 Medical Electrical Equipment – Part 1: General Requirements for Safety: Electromagnetic Compatibility – Requirements and Tests. Both devices shall be compatible with Quinton medical treadmills and selected ergometers. Both devices shall be used in a clinical environment. Electrical and thermal safety of both devices is assured by compliance with IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety. The proposed device is substantially equivalent in safety and effectiveness to the Q-4500 Stress Test Monitor.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 9 2000

David Himes  
Principal Compliance Engineer  
Quinton Instrument Company  
3303 Monte Villa Parkway  
Bothell, WA 98021-8906

Re: K001492  
Quinton Q-Stress, Model 000483  
Regulatory Class: II (two)  
Product Code: 74 DPS  
Dated: May 11, 2000  
Received: May 12, 2000

Dear Mr. Himes:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the

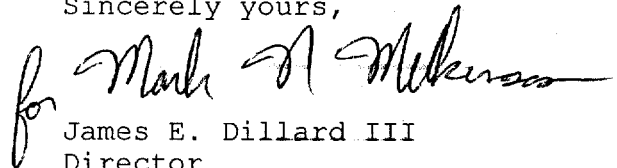
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Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "for Mark D. Mikulas", is written over the typed name and title.

James E. Dillard III  
Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices  
and Radiological Health

Enclosure

510(k) Number (if known): K001492

Device Name: Q-Stress

Indications For Use:

- The device is intended to acquire, process, record, archive, analyze, and output electrocardiographic data during physiologic stress testing.
- The device may interface with external devices, including a treadmill or ergometer for dynamic exercise evaluation, non-invasive blood pressure equipment, and computer communications equipment.
- The device is intended for use in a clinical setting by trained personnel who are acting on the orders of a licensed physician.
- The device is to be used on adult populations, typically symptomatic.
- The device is not intended to be used as a vital signs physiological monitor.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark N. Melkers*  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K001492

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_